

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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MEDTECH PRODUCTS, INC.,  
Plaintiff,  
v.  
RANIR, LLC and CVS Pharmacy, Inc.,  
Defendants.

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07 CV 3302-WP4-LMS  
(Consolidated)

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MEDTECH PRODUCTS, INC.,  
Plaintiff,  
v.  
DENTEK ORAL CARE, INC.,  
Defendant.

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MEDTECH PRODUCTS, INC.,  
Plaintiff,  
v.  
POWER PRODUCTS, INC.,  
Defendant.

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**MEMORANDUM OF DEFENDANT DENTEK ORAL CARE, INC. ON  
CONSTRUCTION OF CLAIM 17 OF THE '051 PATENT**

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## **I. INTRODUCTION**

In this action, Medtech Products Inc. (“Medtech”) asserts infringement of a single claim of a single patent, claim 17 of U.S. Patent No. 6,830,051 (the “‘051 patent”). The patent is directed to a mouth guard that is used at night to prevent tooth damage, something known throughout the industry as a nightguard. In discussing the background of the invention, the patent identifies this type of device, generically, as a nightguard no less than four times in the span of ten lines. (*See* Col. 1, lines 44-54 of the ‘051 patent attached at Ex. A to the Declaration of Gregory Sieczkiewicz, hereinafter, “Sieczk. Decl. at Ex. A”; *see also, id.* at Col. 1, l. 24.) Nightguards are used to minimize tooth damage caused by the involuntary clenching and bruxing (*i.e.*, grinding) of the teeth at night, during sleep. (*Id.* at Col. 1, lines 1-26.)

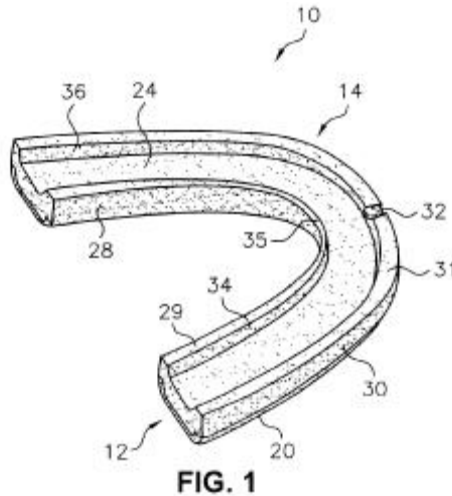
The claim at issue, unlike the other claims of the patent, is not directed to the structural configuration of the device, *per se*, but rather to a method of manufacturing a device out of materials having specific chemical and physical characteristics put together in a specified way. The base is created first, placed in a mold and the impression preform is molded over the base to achieve a better bond and resistance to the shear forces exerted on the device by grinding teeth. The base and impression perform, respectively, must have the physical parameters and chemical composition which the claim specifies for them.

## **II. BRIEF DESCRIPTION OF THE DEVICE AND METHOD OF MANUFACTURE DESCRIBED IN THE PATENT**

The patent states that interocclusal<sup>1</sup> appliances, such as nightguards, have been long recognized as beneficial to alleviating the adverse effects of bruxing and clenching. (Col. 1 at ll. 4-26.) Figure 1 of the ‘051 patent shows the interocclusal appliance to which the ‘051 patent is directed:

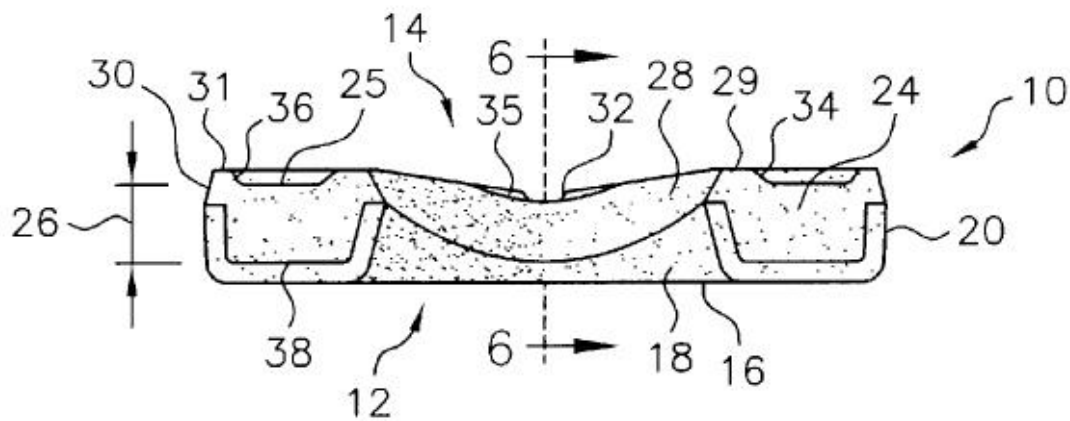
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<sup>1</sup> Interocclusal is a term that relates to being situated between the surfaces of the teeth that are contacted when opposite teeth are brought together. (*See* Sieczk. Decl. at Ex. B).



Reference number 10 generally denotes an interocclusal appliance constructed in accordance with the alleged invention. (Col. 3 at ll. 59-61.) There is a base 12 which is U-shaped, so as to match the maxillary dental arch formed by a user's teeth. (*Id.* at ll. 62-64.) An impression preform 14 is molded over that base to form a unitary structure. (*Id.*) In use, the device is placed in hot water, so that the user can sink his or her teeth into the shallow pilot channel 24 located toward the top of impression preform 14, during self-fitting. (Abstract; Col. 4 at ll. 7-12.) The base has a higher softening temperature than the impression preform. (*Id.*) As a result, the portion of the nightguard into which the user sinks his or her teeth may be softened when placed in hot water, without affecting the structural integrity of the base. (Col. 4, lines 59-63.)

The base 12 features an upper surface 38 and side walls 18 and 20. (Col. 4, ll. 46-60.) These are shown, most clearly, in Figure 5 of the '051 patent, reproduced below:

**FIG. 5**

The impression preform material is bonded to the entire upper surface 38 of the base. (*Id.*) The pilot channel 24 of the impression preform 14 is defined by a generally planar face 25 and a pair of side walls each having an upper ridge. Specifically, they are wall 28 and ridge 29, as well as wall 30 and ridge 31. (Col. 4 at ll. 15-19.)

The physical and chemical characteristics of the materials used to manufacture the interocclusal device and the method of manufacturing are described in the Summary of Invention (*see, e.g.*, Col. 1, l. 65 – Col. 2, l. 8) and in the body of the patent at Col. 4, line 64 *et seq.* The base softens at a higher temperature than the impression preform and has a specified level of hardness, so that when the device is heated to allow the user to make a dental imprint, the base does not become thinner as a result of the force of teeth coming together during fitting. (Col. 4 at ll. 59-63.) Blends containing EVA, among other materials, are entirely suitable. (Abstract; Summary of the Invention at Col. 2, ll. 36-41.)

The Summary of the Invention specifies that the impression preform should be constructed out of an EVA copolymer having approximately thirty percent vinyl acetate. (Col. 2, ll. 3-7.) The Abstract says the same thing. The specification states that the EVA copolymer used in the impression preform is to have a vinyl acetate content of at least 25%, so as to suggest that

25% is an absolute minimum. (Col. 5, ll. 15-20.) Elvax®150 is identified as preferred and stated to contain 33% vinyl acetate content by weight. (*Id.*; *see, e.g.*, Col. 5, line 47, Col. 6, l. 40.)

Relative to the method of manufacture, the thermoplastic resin from which the base is formed has characteristics suitable for injection molding. (Col. 5 at ll. 6-12.) After the base has been formed and placed in the mold, the thermoplastic resin for the impression preform is injected into the mold cavity over the entire top of the base to form the unitary device. (Col. 4, ll. 46-49.) By injection molding in this fashion, the base and preform form a strong bond that will withstand the force exerted by clenching (and grinding) and permit the interocclusal device to remain unitary under the shear forces that apply during use, rather than separate under them. (Col. 5 at ll. 1-12; Col. 10, ll. 39-51.)

Relative to the state of the art, the inventors themselves readily acknowledge in the Background of the Invention that:

Interocclusal appliances, such as nightguards, have been long recognized as beneficial for the alleviation of the adverse effects of bruxism and clenching. (Col. 1, ll. 24-26.)

The inventors also acknowledge that these interocclusal devices were often self-fitted (Col. 1 at ll. 27-28), and were molded out of a base and an impression preform. In describing the nightguards commonly used before the alleged invention at Col. 1, ll. 34-42, the Background of the Invention states:

A typical self fitted interocclusal appliance included a thermoplastic channel trough in the configuration of a maxillary arch. Carried in the trough was a thermoplastic impressionable liner material having a softening point temperature lower than that of the trough. The liner was molded to conform to the mouth of the user after the appliance was immersed in hot water and then inserted into the mouth, with the liner placed against the maxillary arch. The user's jaw was then closed and biting pressure was applied to force the maxillary teeth into the liner.



The problems to which the claimed invention is directed relate not only to the fitting procedure but also the durability of the device. (Col. 1 at ll. 43-46.) The fitting issues related to structural considerations affecting a user's ability to center and align the device. (*Id.* at ll. 46-52.) The durability problems, to which the method of manufacture claimed in claim 17 is directed, arose from separation of the base from the liner caused by the shear forces applied to the device during bruxing (*i.e.*, grinding) and clenching. (*Id.* at 53-62.) As stated at Col. 1, ll. 53-62:

Further problems were encountered with respect to the structural integrity of self fitting nightguards. As a result of the shear forces which were generated during bruxing or clenching events, separation of the bond between the liner and the trough occurred. With the trough in contact with the mandibular occlusal surfaces and the maxillary teeth embedded in the liner, lateral, superior and anterior mandibular deviations during bruxing events resulted in shear stress which separated the liner from the trough, rendering the device unserviceable.

By molding the preform over the entire upper surface of the base a particularly strong bond can be created which is better able to resist the shear forces that apply during clenching and grinding of the teeth. The Summary of the Invention states at Col. 2, l. 65 - Col. 3, l. 5:

Yet another aspect of the present invention is to provide an interocclusal appliance of the general character described suited for extended usage without deterioration.

To provide an interocclusal appliance of the general character described having a base and an impression material unitarily molded thereto and characterized by a high shear resistance bond between components is a still further consideration of the present invention.

In describing the method of manufacture, every example contained in the patent explains that the base is formed first, placed in a mold cavity and the material for the impression preform is injected into the mold so as to mold the preform over the base. As a result the impression preform is formed over the entire upper surface of the base and provides a strong bond for the unitary structure. With reference to Figure 5, the patent states at Col. 4, ll. 46-49:

The upper surface of the base and the opposed inner surfaces of the side walls 18, 20, **all of which are bonded to the impression preform 14 when the preform is molded over the base**, is designated by the reference numeral 38 in Fig. 5. (Col. 4, ll. 46-50, emphasis added.)

The Summary of the Invention itself calls out that the impression preform is “[m]olded into the base **between and above the side walls of the base.**” (Col. 2 at ll. 3-5, emphasis added.) In short, the impression covers the entire surface of the base 38, including the sidewalls. The examples set forth in the patent all specify that the impression preform is manufactured by heating the preform material above its melting point and injecting it over the base situated in the mold to form a high adhesion bond. (*See, e.g.*, Col. 5, ll. 49-57.) The Abstract of the Invention also states that the preform is molded over and unitarily bonded to the base.

The Summary of the Invention begins by characterizing the invention as the combination of a base and a preform in which: a) a base is molded of a thermoplastic material having a relatively high softening temperature and a specified hardness, and b) an impression preform is molded “into the base between and above the side walls” of the base and is comprised of an EVA copolymer having approximately thirty percent vinyl acetate and a relatively low softening temperature. (Col. 1, l. 65 – Col. 2, l. 8.)

These are the features to which Claim 17 is directed. It reads as follows:

17. A method of fabricating an interocclusal appliance for alleviation of the adverse effects of bruxing or clenching events, the method comprising the steps of:

- a) molding and [sic] appliance base from a resin having a Vicat softening temperature of at least 70° C. and a Shore A hardness of at least 80; and
- b) molding over the base an impression preform from a resin comprising an ethylene vinyl acetate copolymer having approximately 30% by weight vinyl acetate.

As revealed in the prior patents cited by the US Patent & Trademark Office (“PTO”) during its consideration of the ‘051 patent, discussed below, there is nothing new about the use

of EVA for an impression preform or an EVA blend in a base. The invention of claim 17 is directed to a method of manufacturing an allegedly improved nightguard by molding an impression perform having specific chemical characteristics over the entire upper surface of a base having specified physical characteristics to make a particularly strong and durable bond capable of withstanding the shear forces exerted by the clenching and grinding of teeth. This is the specific problem which the patent seeks to solve, the separation of the preform impression from the base. (Col. 1 at ll. 53-62.)

### **III. BRIEF DESCRIPTION OF THE PROSECUTION HISTORY WITHIN THE PTO**

#### **A. The Reasons for Allowance**

The application for the patent-in-suit was filed on April 29, 2003. The patent office file indicates that the examiner considered the sixteen earlier U.S. patents identified by the applicants and four additional patents he uncovered through his own search. There is no discussion of what is disclosed in any of those patents by the Examiner, who simply issued a notice of allowability on April 22, 2004, allowing claims 1-17.

The Examiner set forth the following as his Reason For Allowance:

The following is an examiner's statement of reasons for allowance: The prior art does not disclose or suggest in [sic] interocclusal appliance having a base that has a plan configuration of a dental arch and a generally planar occlusal face, impression material bonded to the base, the impression material has a pilot channel having a generally planar face and a pair of space [sic] peripheral walls, the impression material has a footing having a height extending from the opposite face of the base to the face of the pilot channel, the height of the footing being at least twice the distance between the occlusal face of the base and the opposite face of the base.

The footing height is a feature of claims 1-16. The only language in claim 17 to which these reasons for allowance can possibly be directed is "molding over the base an impression preform." Molding a preform impression to a base was old. (Col. 1, ll. 33-43; III. B. *infra*.) Bonding over the entire base to form a pair of spaced peripheral walls was not. Molding in this

fashion to provide a particularly strong bond is the way in which the inventors solved the problem of separation. (Col. 1, ll. 52-62; Col. 2, ll. 3-4.)

**B. The State Of The Art As Reflected In The Prior Art Of Record**

The prior art of record shows little to differentiate claim 17 from what came before it. Many of the prior art references describe an injection molded mouthguard featuring a base having a higher softening temperature which is made of EVA or an EVA copolymer and a liner having a lower softening temperature also made of an EVA composition.

For example, U.S. 5,566,684 (Sieczk. Decl. at Ex. H) describes a mouth guard 10 that includes lower trough 12 of channel-shaped cross-section. At col. 3, ll. 54-64, the '684 patent continues:

The trough 12 may be injection molded of a suitable thermoplastic with a mold temperature in the order of 350° F. Suitable thermoplastics for employment include EVA compositions such as Elvax 260 and Elvax 250.

The mouthguard 10 also includes an upper fill 24 formed of the lower softening temperature thermoplastic which is injection moldable at a lower temperature range, for example, 180° F. through 250° F. An EVA composition, such as Elvax 150 may be employed. The fill 24 is preferably injection molded to the trough 12 by first placing a completed trough into a mold.

U.S. Patent No. 6,082,363 (Sieczk. Decl. at Ex. F) is another example. It discloses a mouthguard which has a base made of a copolymer of EVA. Elvax Resin 350 through 450 is expressly suggested. A soft liner is formed of a material with a lower softening temperature than the base and a copolymer of ethylene and vinyl acetate having at least 33% of vinyl acetate by weight is suggested. ('363 patent at Col. 5, ll. 50-60.) Alternative copolymers of ethylene and vinyl acetate having 40% by weight are also suggested, including a soft EVA 40. (*Id.*) Hence, the EVA content that is preferred is at least 33%. An intermediate frame included to absorb shock is also made of a copolymer of ethylene and vinyl acetate. (Col. 5, at ll. 9-19.)

The '363 patent specifically addresses the benefit of using material in the liner that softens at a lower temperature than the base. ('363 patent at Col. 2, ll. 29-32 and 49-52; Col. 6, ll. 55-58.) Various EVA compounds are called out throughout the patent which can accomplish this, with a liner having a weight percentage of vinyl acetate greater than 33% being preferred. (See Col. 5, ll. 54-60 and Claim 14.)

These are merely exemplary with many of the others being to the same effect. As stated in U.S. 6,036,487, at Col. 1, ll. 18-23 (Sieczk. Decl. at Ex. G): "Mouthguards are typically made from plastics material such as an ethylene vinyl acetate copolymer (EVA) ...." Additional patents expressly referencing EVA are mentioned in the discussion that follows in that patent.

#### **IV. LEGAL PRINCIPLES REGARDING CLAIM CONSTRUCTION**

##### **A. General Principles of Claim Construction**

Claim interpretation is a question of law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996). In interpreting a claim, three sources must be considered: the claims, the specification, and the prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005)(*en banc*). *Phillips* resolved conflicting precedents by holding that the specification of the patent is the best guide to the meaning of the claim terms and that it is improper to elevate dictionary definitions above that. In particular, the *Phillips* court reaffirmed that the specification is the "single best guide" to the meaning of the disputed claim language. *Id.* at 1321 (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). It continues to be proper to give the language of the claims its ordinary and customary meaning, so long as it aligns with the description of the invention in the patent. *Phillips*, 415 F.3d at 1312-13 (citations omitted).

According to the Federal Circuit: "Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors *actually*

invented and intended to envelop with the claim. *The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.*" *Phillips*, 415 F.3d at 1316 (emphasis added). "Where the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims." *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1370 (Fed. Cir. 2003). Therefore, "[i]t is entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Phillips*, 415 F.3d at 1317.

In reviewing the specification, the court may give greater weight to the Summary of the Invention, because "[s]tatements that describe the invention as a whole are more likely to be found in certain sections of the specification, such as the Summary of the Invention." *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 864 (Fed. Cir. 2004). *See also, Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1348 (Fed. Cir. 2004); *Genzyme v. Transkaryotic Therapies, Inc.*, 346 F.3d 1094, 1099 (Fed. Cir. 2003); *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343 (Fed. Cir. 2001) (considering Abstract as well as Summary of the Invention).

The problem the inventor was trying to solve, as discerned from the patent, should be considered so that the claims are construed in a manner that is consistent with, and furthers the purpose of, the invention. *CVI/Beta Ventures, Inc. v. Tura LP*, 112 F.3d 1146, 1160 (Fed. Cir. 1997).

## **B. The Role of the Prosecution History**

Courts naturally study the Examiner's Reasons For Allowance. Where an Examiner states that he is allowing a claim because the prior art fails to show specified features believed to be inventive, and the inventor does not dispute that statement, the Examiner's statement will be

used, as appropriate, to construe the allowed claim. *Koepnick Med. & Educ. Research Found. v. Alcon Labs.*, 162 Fed. Appx. 967, 971 (Fed. Cir. 2005) (Examiner's recitation that prior art does not teach "cutting two disks from the eye" supports construction of "excising" as "cutting out.")

"To be sure, failure to object to an examiner's interpretation of a claim ordinarily disclaims a broader interpretation." *Inverness Med. Switz. GmbH v. Warner Lambert Co.*, 309 F.3d 1373, 1380 (Fed. Cir. 2002) (citing *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 979 (Fed. Cir. 1999) for the holding that "failure to respond to an examiner's reason for allowance functioned as a disavowal of a different interpretation of the claim.")

### **C. The Use Of Extrinsic Evidence.**

Extrinsic evidence, such as expert testimony, is that evidence which is external to the patent and prosecution history. *Vitronics Corp. v. Conceptronic*, 90 F.3d 1576, 1584 (Fed. Cir. 1996). In most situations, analysis of the intrinsic evidence alone will resolve claim construction disputes. *Id.* at 1583. Extrinsic evidence can never be used to reach a result that contradicts the intrinsic evidence. *Id.* Nonetheless, it may be appropriate "for a court to consult trustworthy extrinsic evidence to ensure that the claim construction it is tending to from the patent file is not inconsistent with clearly expressed, plainly apposite, and widely held understandings in the pertinent technical field." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583). Dictionary definitions and other objective reference materials available at the time that the patent was issued may also provide evidence of a claim's ordinary meaning. *Phillips*, 415 F.3d at 1314, 1322-23 ("judges . . . may also rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents") (citations and internal quotations omitted).

**D. Claims Should Be Construed Narrowly Where The Boundaries Are Unclear To Serve The Notice Function Of Claims And Avoid Invalidation For Indefiniteness**

Patent claims define the metes and bounds of the right that the patent confers on the patentee to exclude others from making, using, or selling the patented invention. *Johnson & Johnston Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1052 (Fed. Cir. 2002); *In re Vamco Mach. & Tool, Inc.*, 752 F.2d 1564, 1577 (Fed. Cir. 1985). The second paragraph of 35 U.S.C. §112 requires the claims to particularly point out and distinctly claim the subject matter that the patentee regards as the invention. 35 U.S.C. § 112, ¶ 2. “Distinctly” means that the claim must have a clear and definite meaning when construed in light of the complete patent document. *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985). The definiteness requirement guards against unreasonable advantages to the patentee and ensures that the claims give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, including competitors of the patent, can determine whether or not they infringe. *Athletic Alternatives v. Prince Mfg.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996).

To address just this problem, the law is clear that where there is any doubt as to the propriety of two alternative constructions of the metes-and-bounds of the claim, the narrower interpretation must be taken; both to serve the notice function performed by the claims and to save the claim from invalidity under paragraph 2 of section 112. *Athletic Alternatives*, 73 F.3d at 1581 (“Where there is an equal choice between a broader and a narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrower meaning, we consider the notice function of the claim to be best served by adopting the narrower meaning.”); *Honeywell Int’l, Inc. v. ITC*, 341 F.3d 1332, 1339 (Fed. Cir. 2003); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1342 (Fed. Cir. 2003) (“A



claim is indefinite under § 112 ¶2 if it is insolubly ambiguous, and no narrowing construction can properly be adopted.”) (citations and internal quotations omitted).

Definiteness problems can arise when words of degree are used in a claim. *BJ Servs. Co. v. Halliburton Energy Servs., Inc.*, 338 F.3d 1368, 1372 (Fed. Cir. 2003) (construing “about 0.06”)<sup>2</sup>. In these instances the claim should be defined to correspond to what the specification discloses clearly to persons skilled in the art who want to know the actual boundaries of the patent right. For example, in *Evans Med. Ltd. v. American Cyanamid Co.*, 11 F. Supp. 2d 338, 353 (S.D.N.Y. 1998), *aff’d*, 1999 U.S. App. LEXIS 18436 (Fed. Cir. August 9, 1999), the court stated that “the only intrinsic evidence as [to] the meaning of the terms ... ‘about 1:1’ is the one example given in the specification, in which the ratio of the residue values of the two amino acids is 60:62 (or 0.97:1), which is to say that they are within 3% of one another.” *Id.* at 354. The Court further stated that in the absence of other evidence, the claim construction of “about 1:1” would be determined “by the example in the specification (e.g., +/- 3%).” *Id.*<sup>3</sup>

## V. CONSTRUCTION OF THE DISPUTED CLAIM TERMS

Term or Phrase to be Construed	DenTek’s Construction	Medtech’s Construction
an interocclusal appliance	a device that prevents full occlusion of all teeth	an appliance that is used or fitted, in whole or in part, between portions of the upper and lower teeth

“Interocclusal” is defined as “situated between the occlusal surfaces of opposing teeth.” (Sieczk. Decl. at Ex. B.) Occlusal surfaces are any of the incising and masticating surfaces of the upper and lower teeth. (*Id.*) Consequently, an interocclusal appliance is a device situated between any surface of any teeth that might come into contact.

<sup>2</sup> The Federal Circuit has construed the terms “about” and “approximately” in the same way. *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1326 (Fed. Cir. 2007).

<sup>3</sup> The Court went on to find a range for “about 1:1” of +/- 5% only because defendant had made a statement against interest that it could be construed as +/- 5%.

This interpretation is entirely consistent with the stated objectives of the patent, namely, preventing loss of tooth structure. (Col. 3 at ll. 6-9.) To this end, the interocclusal device is described as having a base in the general shape of a maxillary dental arch and an impression preform 14 that is “transformed into a maxillary dentition encasement during self-fitting of the interocclusal appliance.” (Col. 3 at ll. 59-66; Abstract.) In other words, the interocclusal appliance is described as shaped to match, and to serve to encase, all of the user’s teeth. No embodiment is shown that does not do this and no suggestion is made that anything less is contemplated.

Consequently, the definition of this term in its normal use and the definition which most naturally aligns with the teachings of the ‘051 patent is that an “interocclusal appliance” is a device that prevents occlusion of all teeth. Medtech’s interpretation is incorrect in that the device is not fitted, as Medtech would have it, “...in whole or in *part*, between *portions* of the upper and lower teeth.” (Emphasis added).

Term or Phrase to be Construed	DenTek’s Construction	Medtech’s Construction
bruxing	grinding of the teeth	not construed
clenching	clenching teeth tightly	not construed

The proper construction of “bruxing” is “grinding of the teeth,” and “clenching” is “closing teeth tightly.” (Sieczk. Decl. at Ex. C.) Medtech does not offer a construction, but there is little reason not to differentiate the two terms and explain to the jury what “bruxing” means.

The ’051 patent indicates that lateral and compressive stresses are exerted during bruxing “or” clenching events. (’051 patent, col. 5, ll. 3-5.) The “lateral stresses,” caused by grinding teeth, correspond to the term “bruxing,” while “compressive stresses” correspond to clenching. This is entirely consistent with dictionary definitions. (Sieczk. Decl. at Ex. C.)

Term or Phrase to be Construed	DenTek's Construction	Medtech's Construction
molding and appliance base	<p>as written, this claim is indefinite, vague, and unclear in the recitation of the phrase "molding and appliance base"</p> <p>"molding" means forming a thermoplastic material into a particular shape by injecting the thermoplastic material into a mold</p> <p>"appliance base" means a structure in which the thickness thereof is not significantly reduced by compressive forces applied by biting</p>	a step of molding an appliance base

As written, this claim contains the phrase "molding and appliance base" which is obviously incorrect. Beyond that, it remains unclear whether "and" should be "an" or whether there are two steps within this phrase, a "molding" step and an additional step missing the verb preceding "appliance base." The file history of the '051 patent reveals that this phrase was present in the application as originally filed and was not corrected during the prosecution of claim 17. (Sieczk. Decl. at Ex. D, page 37.) It was the patentee's obligation to correct this error by way of certificate of correction or reissue, which applicants did not.

Should the Court interpret this phrase as "molding an appliance base," "molding" means forming a thermoplastic material into a particular shape by injecting the thermoplastic material into a mold wherein the material conforms to the shape of the mold as it hardens. The "appliance base" is the resultant structure that serves as the base of the interocclusal appliance. The patent states: "in accordance with the present invention, the base 12 is formed by injection molding a thermoplastic resin having requisite characteristics into a base mold cavity." ('051 patent, col. 5, ll. 6-12.) Furthermore, the '051 patent is replete with examples specifying that the

base was injection molded into a mold cavity utilizing specified resin formulations. ('051 patent, col. 6, ll. 11-12 and 33-47; col. 7, ll. 2-3, 19-33 and 55-56; col. 8, ll. 5-22, 47-48 and 65-67; col. 9, ll. 1-15, 37-38 and 53-67; col. 10, ll. 1-3.)

In the context of the claim, the base is intended to be a structure in which the thickness thereof is not significantly reduced by compressive forces applied by biting. This is implicit in the Vicat softening temperature and Shore A hardness limitations. (See Col. 4, ll. 59-63.) A more precise definition might be that "appliance base" means a structure "used as the base of an interocclusal appliance" in which the thickness thereof is not significantly reduced by compressive forces applied by biting.

Term or Phrase to be Construed	DenTek's Construction	Medtech's Construction
a resin	a synthetic organic compound consisting of a noncrystalline solid or viscous liquid substance	a moldable material

Within the specification, resins are described by chemical and physical characteristics, including softening temperatures and hardness; the resins are also referred to as "thermoplastic." ('051 patent, col. 4, ll. 64-67; col. 5, ll. 6-12.)

However, the Summary of the Invention and the Abstract only disclose the following synthetic organic compounds as suitable for use: "[s]uitable thermoplastics for employment as the base include ELVALOY®/EMA copolymer, ELVALOY®/EMA blended with ELVAX®/EVA or ELVALOY®/EMA blended with PELLETHANE® TPU elastomer." ('051 patent, col. 2, ll. 37-41.) The Encyclopædia Britannica defines resin as "any natural or synthetic organic compound consisting of a noncrystalline or viscous liquid substance." However, this definition would also appear to be limited by the description of the '051 patent, as to which

resins are suitable - synthetic organic compounds. Hence, Dentek's construction is fairly technical.

The '051 specifies that the resin used to form the appliance base and the impression preform are both moldable when heated. ('051 patent, col. 5, ll. 32-53.) Therefore, DenTek's construction might be better understood without loss of accuracy by defining it as a synthetic organic thermoplastic compound. The dictionary definition of resin describes a class of synthetic products (chemically different from natural resins) that may be thermoplastic or thermosetting. (Sieczk. Decl. at Ex. C.)

Regardless, Medtech's proposed construction is plainly overbroad and cannot be correct. There are many materials that may be "a moldable material" and are not made of resin.

Term or Phrase to be Construed	DenTek's Construction	Medtech's Construction
having a Vicat softening temperature	a temperature at which a flat-ended needle penetrates the hardened resin to the depth of 1 mm under a specific load when the hardened resin is heated	the temperature at which a flat-ended needle penetrates a specimen of the resin to the depth of 1 mm under a 10 Newton load, under ASTM D1525 standard

DenTek's proposed construction is consistent with the American Society for Testing and Materials' standard ASTM D 1525, "Standard Test Method for Vicat Softening Temperature of Plastics," ASTM International, 2007. This standard is expressly mentioned in the specification (Col. 4 at ll. 64-67.) Medtech's proposed construction, while superficially similar to DenTek's proposed construction, is deficient in two regards. First, the Medtech construction fails to specify that the resin specimen must be measured when hardened. The testing methods performed under ASTM D 1525 are designed to measure a temperature point at which a given solid will soften, and are inapplicable to non-solids, including resins in viscous liquid form. Second, Medtech's construction fails to specify that the hardened resin is heated; the heating step is of significance

in that the '051 patent specifies that the interocclusal appliance is heated to a temperature of 40°C to 46°C during the fitting procedure. ('051 patent, col. 4, ll. 64-67.)

Term or Phrase to be Construed	DenTek's Construction	Medtech's Construction
of at least 70°C	a temperature of 70.0°C or more	a minimum Vicat softening temperature

The accuracy of DenTek's proposed construction is self-evident. Medtech attempts to rewrite the language of the claim so that it would read, in pertinent part, "b) molding and appliance base from a resin having a **minimum Vicat softening temperature** and a Shore A hardness of at least 80," when the claim actually reads "b) molding and appliance base from a resin having a **Vicat softening temperature of at least 70** and a Shore A hardness of at least 80," The Medtech construction rewrites the claim language, impermissibly, into something which is unclear and indefinite because the metes and bounds of a claim that does not attach a numerical value to "minimum" in the context of a Vicat softening temperature are indeterminate.

Term or Phrase to be Construed	DenTek's Construction	Medtech's Construction
a Shore A hardness	a measurement of the extent of indentation of a hardened resin by the action of a Shore A durometer	a measurement of hardness using a TMI Duromotor model number 4150 equipped with a Shore Durometer Hardness Type A

DenTek's proposed construction of the term "a Shore A hardness" should be adopted because it is the construction most consistent with the American Society for Testing and Materials' standard ASTM D 2240, "Standard Test Method for Rubber Property—Durometer Hardness," ASTM International, 2007, which provides that the durometer measures the extent of indentation of a material; such measurement is then used to describe the relative hardness of the material. An ASTM standard suggests itself here since ASTM is a sanctioned standards body and an ASTM standard was suggested elsewhere in the patent. (See Col. 4 at ll. 64-67.) The

meaning of TMI is not known and Medtech's construing "a Shore A hardness" to a specific model of durometer manufactured by a specific company is unsupported by the claims of the '051 patent, the file history, or any extrinsic evidence, and should therefore be disregarded.

Term or Phrase to be Construed	DenTek's Construction	Medtech's Construction
of at least 80	a Shore A hardness of 80 or more	a minimum Shore A hardness

DenTek's proposed construction of the term "of at least 80" in relation to a Shore A hardness of the resin used to mold the appliance base is straightforward. Medtech again would rewrite the language of the claim into something other than what it actually is. The result is illogical and renders the claim indefinite because one cannot determine the scope of the claim without attaching a numerical value to a minimum Shore A hardness.

Term or Phrase to be Construed	DenTek's Construction	Medtech's Construction
molding over the base	contacting a heated resin with the entire upper surface of the appliance base	a step of molding over the base

Properly construed, "molding over the base" is contacting a heated resin with the entire upper surface of the appliance base. The '051 patent explains that the top surface of the base serves as the mold to which the bottom of the preform impression conforms and bonds:

in accordance with the present invention, the base 12 is formed by injection molding a thermoplastic resin having requisite characteristics into a base mold cavity. The molded base 12 is positioned in an occlusal appliance mold cavity and a thermoplastic resin having the requisite characteristics for the impression preform 14 is injected into the appliance mold cavity over the base 12 and unitarily bonds thereto. ('051 patent, col. 5, ll. 6-12.)

The result is that the impression preform bonds to the entire upper surface 38 of the base, including the side walls. The Summary of the Invention is completely clear on the point and is entitled to particular weight under the authorities cited *supra* at p. 10:

Molded **into the base between and above the side walls** is an impression preform comprising an EVA copolymer having approximately thirty percent vinyl acetate.... (Col. 2, ll. 3-4) (emphasis added.)

The specification of the patent also could not be clearer:

The upper surface of the base and the opposed inner surfaces of the side walls 18, 20, **all of which are bonded to the impression preform 14 when the preform is molded over the base**, is designated by the reference numeral 38 in Fig. 5. (Col. 4, ll. 46-50) (emphasis added.)

Every embodiment described in the patent does this and no other configuration is suggested. The Background of the Invention explains that the problem solved by the invention was to prevent the separation of the bond between the impression preform and base under the shear forces applied to the device during clenching and bruxing. (Col. 1, ll. 53-62.) The body of the patent emphasizes this as well, noting that “the surface 38 of the base over which the impression preform is molded” can be coated or textured to promote bonding. (Col. 10 at ll. 39-51.)

The Summary of Invention states that an objective of the invention is to solve the problem of separation. (Col. 2, l. 65 – Col. 3, l. 4.) *See CVI/Beta Ventures, Inc.*, 112 F. 3d at 1160. Placing the base in the mold cavity and molding the impression preform over its entire upper surface to create a better unitary bond is part of the solution. (Col. 5, at ll. 1-12.) Every example provided does just this and emphasizes the strength of the resultant bond. As stated in relation to Example No. 1:

The ELVAX® 150 EVA was heated to a recommended molding temperature above its melting point and injection molded into an occlusal appliance mold cavity over the molded base positioned within the mold cavity. The unitary interocclusal appliance removed from the mold cavity exhibited a high adhesion bond between the base and the molded over impression preform, both before and after fitting. (‘051 patent, col. 5, ll. 53-57.)



Virtually identical language is used in every other example. (Col. 6, ll. 44-50; Col. 7, ll. 29-36; Col. 8, ll. 16-23; Col. 9, ll. 9-14 and Col. 9, l. 64 – Col. 10, l. 3.)

The verb form of the term “molding” is most relevantly defined as “to fit the contours of.” (Sieczk. Decl. at Ex. C.) Here, the heated resin fits closely to the entire upper surface of the appliance base by following the contours of the base to form a stress-resistant unitary interocclusal appliance. Furthermore, the adverbial use of the word “over” is consistent with the dictionary definition of “so as to cover, conceal or affect the whole surface or expanse.” (Sieczk. Decl. at Ex. C.)

The PTO Examiner’s Reasons for Allowance support DenTek’s construction as a matter of law. (*See* IV. B. *supra*.) The only language in claim 17 that relates to the Examiner’s Reasons For Allowance is the phrase “molding over the base an impression preform.” The Examiner’s statement of reasons for allowance, included the statement that the prior art did not show “impression material bonded to the base,” and that “the impression material has a pilot channel having a generally planar face and a pair of space (sic) peripheral walls.” (Sieczk. Decl. at Ex. D, page 55.) That pair of spaced walls is formed only because the impression perform material completely covers the base and is molded over the walls over the base. Otherwise stated, the impression material has spaced peripheral walls that sit over the walls of the base, as well as a pilot channel that sits over the rest of the base, so that the entire surface of the base is bonded to the impression preform to provide a strong unitary bond. (*See, e.g.*, Fig. 5.) DenTek’s view of the meaning of the claim language is the view the Examiner took in stating his Reasons For Allowance, a view that controls as a matter of law. *Inverness Med. Switz. Gmbh*, 309 F. 3d at 1380; *Koepnick Med.*, 162 Fed. Appx. at 971.

Medtech's construction is circular and unhelpful. It should be noted that Medtech, in its construction of the term "an impression preform," describes the preform as "a formable material overlying the base," not "a formable material overlying a part or a portion of the base."

Term or Phrase to be Construed	DenTek's Construction	Medtech's Construction
an impression preform	a hardened resin structure containing a channel with curving sides and a flat bottom, and a footing that extends from a horizontal upper surface of the base to the channel face	a formable material overlying the base

DenTek's construction attempted to conform to the Reasons for Allowance and the written description contained in the '051 patent, but might be more precisely stated as a hardened resin structure having spaced peripheral walls that may be softened to conform to the shape of the maxillary dentition and encase it during self-fitting. *See* '051 patent at Col. 3, ll. 64-67; and Col. 4, ll. 55-58. To fit the maxillary dentition impression, the preform has a channel defined by sloping (*i.e.*, curving) peripheral (*i.e.*, side) walls and a planar face (*i.e.*, a flat bottom) ('051 patent, col. 2, ll. 8-13) and a footing extending from the flat bottom to the top of the appliance base. ('051 patent, col. 2, ll. 8-9.)

In the Reasons for Allowance, the Examiner stated, in relation to claim 17, that the prior art did not show impression material bonded to the base where the impression material has "a generally planar face and a pair of space[d] peripheral walls." The Examiner's interpretation, which the patentee did not dispute, is now controlling. The impression perform must, as a matter of law, include a pair of spaced peripheral walls. *Inverness Med. Switz. GmbH*, 309 F.3d at 1380.

The term “formable material” is not present in the claim or the written description of the ‘051 patent, and does not have any art-recognized meaning such that it aids in the construction of the phrase.

Term or Phrase to be Construed	DenTek’s Construction	Medtech’s Construction
comprising an ethylene vinyl acetate copolymer	a single type of heteropolymer containing ethylene hydrocarbons interspersed with acetate groups, which does not include a mixture of two different types of such heteropolymers	a resin made of copolymers of ethylene vinyl acetate

The term “ethylene vinyl acetate copolymer” is not specifically defined in the ‘051 patent. A copolymer is defined as a polymer composed of polymer chains made up of two or more chemically different repeating units (*i.e.*, monomers) that can be in different sequences. (Sieczk. Decl. at Ex. B.) In ethylene vinyl acetate, the monomers are ethylene hydrocarbons and acetate groups.

The written description of the ‘051 patent indicates that “[s]uitable resins for employment as the impression preform include an ethylene vinyl acetate (EVA) copolymer available from the Du Pont under the trademark ELVAX® having a vinyl acetate content of at least 25%,” and that a “preferred EVA copolymer is ELVAX®150 having a 33% vinyl acetate content by weight, a Vicat softening temperature of 36°C and a Shore A hardness of 73.” (‘051 patent, col. 5, ll. 12-19.) The Summary of Invention is to the same effect. (‘051 patent, col. 2, ll. 36-41.)

All that the patent describes as suitable and all that the patent encompasses is a single type of ethylene vinyl acetate heteropolymer and not a mixture of two different types of such heteropolymers.

Term or Phrase to be Construed	DenTek's Construction	Medtech's Construction
having approximately 30% by weight vinyl acetate.	having at least 25.0% by weight vinyl acetate but not more than 33.0% by weight vinyl acetate	the resin has approximately 30% by weight vinyl acetate

The Summary of the Invention ('051 patent at Col. 2, ll. 5-6) and the Abstract specify that the resin from which the impression preform is molded is to be "approximately 30% by weight vinyl acetate." The patent does not expressly define the range set by the term "approximately." However, the '051 patent sets the absolute minimum VA content at 25% by weight. (*Id.* at Col. 5, ll. 13-16.) The patent also specifies that a single EVA-containing resin, 100% ELVAX®150, which is claimed in the '051 patent to be 33% VA by weight (*e.g.*, '051 patent, col. 5, ll. 13-17) is preferred. No higher percentage is suggested or mentioned and, in actuality, the VA content of ELVAX®150 is stated by the manufacturer to be 32% VA by weight. (Sieczk. Decl. at Ex. E.)

According to the specification, "approximately 30% by weight vinyl acetate" encompasses a range having a minimum of 25.0% by weight vinyl acetate, and a maximum of 33.0% by weight vinyl acetate. The prior art supports this view since the '363 patent is directed to an interocclusal device with an impression preform in which the percentage by weight of vinyl acetate is preferably greater than 33% (*see* III. B., *supra*) while the percentage by weight of vinyl acetate disclosed by and claimed in the '051 patent is 33% or less. Both the Summary of the Invention and the Abstract chose to characterize the invention as a VA content of "approximately 30%," and not "approximately 33%."

Furthermore, expanding the scope of the term "approximately 30% by weight" beyond the range of 25% to 33% would leave the claims insolubly ambiguous as to how much vinyl acetate could be present without infringing the claim. The public would be left to guess as to the

scope of the claims and the patentee would be permitted to expand the scope of the claims indefinitely. Such a construction runs contrary to the notice function of claims and would render the claim invalid under the second paragraph of 35 U.S.C. § 112. *Athletic Alternatives*, 73 F.3d at 1581; *Amgen*, 314 F.3d at 1342. The language “approximately 30%” is properly construed so as to conform to the range expressly called out in the specification of the patent – 25% to 33%, and no further. *Evans Med. Ltd.*, 11 F. Supp. 2d at 353, *aff’d*, 1999 U.S. App. LEXIS 18436 (Fed. Cir. August 9, 1999).

## VI. CONCLUSION

For all the reasons stated, Dentek respectfully requests that each of its proposed constructions be adopted.

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**CERTIFICATE OF SERVICE**

I hereby certify that on July 13, 2007, I caused a true and correct copy of the  
**MEMORANDUM OF DEFENDANT DENTEK ORAL CARE, INC. ON  
CONSTRUCTION OF CLAIM 17 OF THE '051 PATENT** to be served upon the  
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